

**Case Study:**  
**Iso 14000 - Benefits To The Bottom Line**

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**INTRODUCTION**

Many organizations have developed an understanding of ISO 14000 and the potential benefits of corporate environmental management in today's global economy. This paper is a case study of an ISO 14000 program at a major pharmaceutical manufacturer. It focuses specifically on what spurred the decision to develop the program, the different program steps and requirements, and the financial and other benefits derived.

The environmental department of this pharmaceutical manufacturer was in a "reactive" mode, spending more than half of every working day with environmental compliance recordkeeping and other clerical duties. Increases in regulatory and corporate requirements ensured that these tasks would only add to the burdens of a department perceived as a drain on profits. Likewise, creativity and enthusiasm were stifled. Overall, the department felt that it could play a greater role in its firm's success.

When the facility environmental manager learned of ISO 14000 through a public seminar, he proposed a program for the facility to become ISO 14000 certified. The goals of the program included operating procedure development and implementation, continuous improvement in management systems through effectively using existing resources, cost control and cost improvement, and perhaps most importantly, forward-thinking. These steps are transforming the environmental department functions into a revenue-generating mindset, which has helped to improve the financial performance of the company. The tasks followed in developing the program are outlined below.

**EVALUATION STAGE**

In order to decide on whether to proceed and to accurately plan for implementation, it was necessary to assess and evaluate existing conditions at the facility.

**Task 1: Educate Management**

The initial step in developing the ISO 14000 program was to obtain top management commitment to pursue an inquiry toward implementing an effective program via awareness training. The goal of this training was to help management develop an understanding of the program and convince them of the need to at least proceed with data gathering. This commitment was obtained through a three-hour executive training session. The session introduced ISO 14000 and its core elements, how to implement the program, strategic benefits, and accreditation and certification procedures. It was also important to learn about facility and corporate goals, what was expected as a final product, and what type of support was needed. Once management commitment was obtained, the relatively inexpensive initial review was performed in Tasks 2 through 4.

**Task 2: Gap Analysis**

The gap analysis is a very short and straightforward process. The goal of the gap analysis is to quickly obtain an overall assessment of the company's current environmental management activities in comparison to the ISO 14000 standard requirements. This was accomplished through a review and comparison to each requirement of the standard and completion of a questionnaire about these requirements.

Specifically, the work under this task included the following. Note that none of these tasks were focused solely on regulatory issues:

- Briefly reviewing and comparing the following to the appropriate sections of ISO 14001:
  - The company's environmental policy
  - Current management system procedures and structure and whether the procedures were documented and implemented.
  - Current environmental management records related to the site
- Determining the in-house capabilities and organization of the company's personnel and processes.
- Conducting a closing meeting to inform the company of any findings identified during the assessment and preliminary report on the gap analysis results.
- A graphical presentation and a written report outlining all pertinent findings, conclusions, and recommendations.

To conduct the gap analysis, each requirement of the standard (each "shall") was converted to question form. Rather than a "yes" or "no" answer, the responses were rated on the scale below.

- 5 - conformant to ISO 14000
- 4 - procedure implemented but not documented
- 3 - procedure documented but not implemented
- 2 - no procedure
- 1 - no answer/not known

This scoring system provides a better understanding of the existing gaps, which in turn provided for more accurate implementation planning. Answers to these questions were graphed to provide a detailed method to assess any subelement and visually compare all subelements within each major element. The graphs provided an effective method of communicating the company's status in relation to the ISO 14000 standard.

### **Task 3: Aspect Analysis**

ISO 14000 requires that a facility or site establish and maintain a procedure to identify environmental aspects of activities, products and services ". . . in order to determine those which have or can have significant impacts on the environment" (ISO 14000, Section 4.3).

The aspect analysis is a general data gathering to establish the site's environmental interactions as opposed to a comprehensive audit or assessment. An *environmental aspect* is any element of the organization's activities, products, and services that can interact with the environment that can be controlled or influenced. The impact is the change that occurs in the environment, positive or negative, and is not based on compliance. Current as well as potential aspects and impacts were identified.

For the initial assessment, environmental aspects were identified that applied to company activities, products, and services. These aspects were then sorted into various aspect categories such as air emissions, water releases, solid and hazardous waste, ecosystem interaction, energy, and natural resources. Related impacts on the environment were then identified for each aspect.

Specifically, the aspect analysis procedure involved:

- Review of the site operations to prepare a list of categories for activities, products and services. These categories included manufacturing and production, chemical storage, wastewater treatment, and product transportation, among others.

- Interviews with appropriate personnel and a site reconnaissance to identify the facility's various operational units that interact with the environment. Migration and transport pathways and environmental receptors were noted to document how the activity, product, or services were identified as relevant.
- Review of documented corporate environmental policies and related documents (performance standards, procedures, and compliance management tools) to assist in determining the facility's environmental character.
- Preparation of tables which presented the facility's aspects and associated impacts, sorted by activity, product, or service.

From the list of aspects, the company determined which were significant. These significant aspects were then used to build objectives, targets, and the ISO 14000 program as a whole. The significance of the environmental aspects depended on a variety of considerations related to the business and its environmental issues. Strictly speaking, ISO 14000 did not require use of enumerated criteria to determine significance. It was up to the company to apply appropriate criteria and determine significance through a framework that made sense to the business, the nature of the environmental aspects and impact risks, regulatory and legal liability factors, and the interests of the community and other stakeholders.

**Compliance Assessment:** Because compliance with regulations and other requirements is so important to an effective environmental management system in the United States, the company conducted a regulatory compliance review at the facility to evaluate compliance with local, state, and federal environmental regulations. ISO 14000 requires that compliance monitoring be a component of Monitoring and Measurement (Checking and Corrective Action, Section 4.5: "The organization shall establish and maintain a documented procedure for periodically evaluating compliance with relevant environmental legislation and regulations." Also, the standard requires a commitment to regulatory compliance (Policy, Section 4.2).

A compliance review was an appropriate supplement to the initial aspects analysis to determine baseline conditions. During implementation, aspects analysis and compliance auditing procedures were prepared to be part of the documentation, so that these functions can be repeated in the future. In other words, the standard required developing procedures for those tasks. However, to effectively begin EMS implementation, the aspects analysis and compliance audit had to be conducted at an early stage; therefore, the procedures used in this early assessment were incorporated later into EMS documentation.

#### **Task 4: Detailed Implementation Plan and Timetable Development**

Once the gap analysis and aspect analysis were completed, an accurate implementation plan was developed. Specifically, this included:

- Timetable of implementation.
- Allocation of internal and external resources and costs throughout the implementation period.
- A presentation to management to discuss findings of the initial assessment and implications of the implementation plan. This presentation gave management another opportunity to decide whether to proceed with implementation.

Once a decision was made to proceed with ISO 14000, and resources and personnel were allocated, the implementation plan began. The plan was based on four key factors: planning, implementation, checking, and continual improvement. Using the information collected in the initial assessment, appropriate procedures and

documents were prepared and audited. The following tasks follow the sequence necessary to systematically develop and implement the ISO 14000 program.

## **IMPLEMENTATION STAGE**

Once the decision was made to proceed, the Implementation Stage began. This stage involved developing ISO 14000 program documentation and deploying the system into the organization's operations. These steps are described in detail in Tasks 5 through 16.

### **Task 5: Develop Environmental Policy**

Using the understanding of ISO 14000 and the information collected in the initial assessment, the organization's personnel developed a policy that met ISO 14000 requirements.

According to the policy, the company was committed to being environmentally responsible corporate citizens by:

- Being proactive in efforts to improve production processes to eliminate waste
- Seeking out and considering current technologies in:
  - Environmentally preferred packaging
  - Reusable material handling and recycling systems
  - Waste water discharge reduction
  - Solid waste handling and disposal
  - Hazardous materials handling and storage

The company also declared its intent to use these technologies to move toward the goal of "zero waste discharges by converting today's waste into tomorrow's opportunities."

### **Task 6: Objectives, Targets, and Development of Environmental Management Programs**

With the baseline information and policy in hand, the company established specific objectives and targets and a schedule for achievement and review. Objectives consisted of goals the organization set for itself, based on its environmental policy and significant aspects. The related targets included performance goals and milestones for measurement.

The company reviewed current objectives, targets, and other existing environmental goals to determine ISO 14000 conformance and ensure consistency with what were identified as significant environmental aspects and policy. Assistance in developing additional objectives and targets, as needed, was also included in this task. Objectives and targets were developed where a significant environmental aspect was not already addressed in Task 3.

The environmental aspect analysis findings resulted in two significant aspects and related objectives: reduce offsite wastewater discharges and reduce solid waste generation and disposal. To help achieve these objectives, the following sub-objectives were identified:

- Conduct effluent/waste survey.
- Conduct alternatives and feasibility review of reduction options.
- Review options to reduce water consumption.
- Review options to reduce effluent/waste.
- Prepare capital and maintenance needs for selected option(s).
- Prepare plans and implement selected alternative(s).
- Monitor pending regulations or ordinances regarding effluent/waste streams.

The findings of the compliance audit in Task 3 indicated that another company objective was to continue to monitor and maintain regulatory compliance. To help achieve this objective, other objectives were identified, which included:

- Keep regulatory matrix complete and current.
- Address specific findings in the previous audit, as appropriate.
- Prepare for the upcoming compliance audit.

#### **Task 7: Documentation Training**

Properly and effectively communicating procedures was one of the key ways to ensure employee buy-in and continuous improvement. Accurately preparing the appropriate documents and procedures was therefore a critical step. Training and assistance with preparing procedures was a key way to help in program development.

#### **Task 8: Development of Documentation (Operational and Management Procedures, and Work Instructions)**

Current procedures, work instructions, and standard operating procedures associated with environmental activities were reviewed to focus on identifying areas where adjustments were needed to conform to the ISO standard. Although there was some interviewing in this task, most of the effort was reviewing documentation.

ISO 14000-specific procedures were written and current procedures were modified to address the standard's requirements. A significant effort was needed in developing most of the upper level, ISO 14000-specific documents including the environmental manual and the Level II procedures detailing program auditing, developing objectives and targets, aspects determination, program checking, corrective action, and management review.

The company researched, rewrote, edited, and reorganized all current policy and procedures manuals. This effort involved compiling and cataloging all the material, deleting redundancies and inconsistencies, and working with subject matter experts to communicate technical material correctly, clearly, and concisely. It was important for the company to focus on the effective documentation aspect by producing easily readable documents and suitable training material.

#### **Task 9: Implementation**

This is the actual deployment of the ISO 14000 program into the organization. This step is predominantly being performed by the company staff as part of normal operational responsibilities. This task is usually process-specific, involving small groups addressing particular items or aspects. Also included is the introduction of new or revised work instructions. This task's goal is to ensure that the system, as documented, is in place throughout the organization. It is important during implementation to synchronize processes and personnel with procedures in place. Having the business units and all employees work together to develop the system led to consistency throughout the company and a more effective ISO 14000 program.

#### **Task 10: Employee Overview Training**

An important element of ISO 14000 was to educate all employees, from the top to shop floor, to ensure that everyone in the company was familiar with the program. Its applications and each person's role in making the system were defined to make it functional and effective.

A one-hour overview session (several are needed to cover all employees) introduced the ISO 14000 general concept and the company's position. This training was not operation-specific, but introduces all employees to the ISO 14000 project.

**Task 11: Internal Auditor Training**

ISO 14000 requires that the program be periodically internally audited, independent of any third-party certification program. Although outside consultants could be used, the organization assembled its own internal audit team to conduct the audits supplemented with oversight and support as needed. A two-day training session was conducted for the selected cross-functional internal audit team.

**Task 12: Conduct Internal Audits of the ISO 14000 Program**

Internal audits are being conducted in conjunction with the auditor training to provide a hands-on way to use the techniques learned. The training and the initial internal audits are coordinated for efficiency. The intent of the audits was to assess the program and its conformance to the ISO 14000 standard. These audits were not performance or regulatory compliance audits.

**Task 13: Take Corrective Action**

In this task, nonconformances identified during the auditing process are corrected. The company is addressing the nonconformances identified through the internal audits, monitoring measurement procedures, and other information sources and is taking the appropriate action. Corrective action in this context refers to improvements in the ISO 14000 program.

**Task 14: Pre-Assessment Audit**

A pre-certification audit was conducted in June 1997 to identify any remaining nonconformances and prepare the site for the certification audit. Additional corrective action was taken after the pre-assessment audit. The organization used the selected registrar to conduct the pre-assessment audit, to provide an objective, fresh review of the system.

**Task 15: Formal Registrar Assessment**

This task involves retaining an accredited auditor to perform the third-party certification audit. This effort requires that appropriate company staff be available, as the auditors prefer not to interview external consultants, but instead want to ensure that the organization is familiar and comfortable with their program.

EnSafe strongly encouraged the company to identify a registrar early in the implementation process to avoid disagreements in philosophy and surprises at the end. Whether the company maintains the certificate beyond the initial certification will depend on market needs.

**Task 16: Continuous Improvement**

This is the company's ongoing task and involves researching other systems, benchmarking, developing strategies to achieve goals, establishing future corporate requirements, and linking them to environmental issues.

The ongoing maintenance of the program, including periodic internal audits and third-party surveillance audits, has yet to be addressed. However, as it is implemented, the program becomes standard operating procedure and resources for these functions are incorporated into the environmental business function, which is already providing benefits.

## CONCLUSION

The entire ISO 14000 process, from Task 1 through Task 16, has taken 18 to 22 months to complete. The company spent approximately \$60,000 in direct costs implementing the program to date. However, annual savings of more than \$250,000 from this program more than justified its scope and effort. The company also received favorable feedback from state and federal environmental agencies.

Changes implemented to date have already benefitted the organization more tangibly in the following ways:

- CFCs were converted to Class I refrigerants, a computerized program was implemented to track refrigerant usage and repairs, and emission tracking software and emissions flow charts were put in place. These programs eliminated CFCs, reduced other emissions, and improved the system efficiency by 25% to 35%, resulting in annual net savings of \$164,000.
- Increased efficiency led to a decrease in natural gas usage and electrical demand, resulting in a net annual savings of \$139,000.
- Waste minimization reduced plant waste by 34% from the 1994 baseline level, which resulted in net annual savings of \$100,000.
- Increased recycling rates from 68% to 75% resulted in a net annual savings of \$15,000.

The ingrained management framework and philosophy of continuous improvement ensures that opportunities for increased savings and efficiency will be identified in the future. This is particularly evident in the company's stated goal of zero waste discharges. The environmental department is now recognized as a revenue-generating department, which directly contributes to profitability. In addition, the company realized intangible benefits from improved morale and favorable public perception. The company is currently considering implementing ISO 14000 internationally, using this site as a pilot facility.